

1       HERNIA PROSTHESIS

2

3       **FIELD OF THE INVENTION**

4

5       The present invention relates to prostheses for  
6       repairing or resisting the formation of bodily  
7       hernia in particular, but not exclusively, for  
8       inguinal hernia repair or femoral hernia repair and  
9       a method of using said prostheses.

10

11       **DISCUSSION OF THE PRIOR ART**

12

13       A hernia is due to an abnormal protrusion of an  
14       organ or part thereof through its containing  
15       structure, due to a rupture or weakening in a layer  
16       of fascia creating an aperture or a defect in the  
17       fascia which causes it to be less able to contain  
18       the organ or part thereof. Hernia can occur at  
19       various anatomical positions in the abdomen where  
20       there is a weakness in the muscle, and are  
21       classified according to the site in which they  
22       occur.

1

2 Two particular types of hernia are inguinal hernia  
3 and femoral hernia.

4

5 Inguinal hernia occur in the groin when a portion of  
6 bladder, bowel or membrane pushes through a weak  
7 spot in the abdominal musculature around or at the  
8 inguinal canal. The inguinal canal is an opening  
9 between layers of abdominal muscle near the groin  
10 through which the spermatic cord passes in the male.  
11 Typically, inguinal hernia is a male condition.

12

13 Two particular types of inguinal hernia occur,  
14 direct inguinal hernia and indirect inguinal hernia.

15

16 An indirect inguinal hernia passes through the  
17 internal ring of the inguinal canal, along the canal  
18 and, if the hernia is large enough, emerges through  
19 the external ring and in the male descends into the  
20 scrotum.

21

22 A direct inguinal hernia differs from an indirect  
23 inguinal hernia as it pushes its way directly  
24 forwards through the posterior wall of the inguinal  
25 canal. Occasionally, in unusual circumstances, a  
26 direct hernia becomes large enough to push its way  
27 through the external ring and then into the neck of  
28 the scrotum.

29

30 The femoral artery and vein enter the femoral  
31 triangle from beneath the inguinal ligament within a  
32 fascial tube termed the femoral sheath. The femoral

1 canal is a small, almost vertically-placed gap in  
2 the medial part of the femoral sheath. The function  
3 of the femoral canal is to firstly act as a dead  
4 space for expansion of the distended femoral vein  
5 and secondly as a lymphatic pathway from the lower  
6 limb to the external iliac nodes.

7  
8 The femoral canal is a potential point of weakness  
9 in the abdominal wall which may develop a femoral  
10 hernia. The canal is around 1 to 1.5 cm in length.  
11 As the female pelvis is of greater width than the  
12 male pelvis, the femoral canal can be somewhat  
13 larger in females and female femoral hernia are more  
14 common. A femoral hernia is a protrusion through the  
15 femoral canal. The hernia sac may extend through  
16 the femoral canal.

17  
18 Hernia repair generally requires the contents of the  
19 hernia to be eased back into position and then for  
20 the weakened area to be repaired. Repair can be  
21 effected by tension or tension-free suturing of the  
22 tissue and muscle to strengthen the weakened area or  
23 occlude ruptured areas. Alternatively, the weakened  
24 or ruptured area can be reinforced using a portion  
25 of synthetic mesh.

26  
27 Meshes for use in the treatment of an inguinal or  
28 femoral hernia typically consist of a flat portion  
29 of mesh for application over the hernia area. The  
30 mesh allows a tension free repair to be made of the  
31 weakened area. Such flat meshes have been provided  
32 with an aperture therein or may be cut by a surgeon

1 to allow the mesh to be arranged around an  
2 anatomical structure which passes through the  
3 opening or defect in the tissue, muscle or organ  
4 wall requiring repair or support.

5

6 Alternatively, for a well circumscribed defect, e.g.  
7 a deep inguinal hernia or femoral hernia, the repair  
8 device may be an implantable prosthesis which stops  
9 the rupture hole of the hernia.

10

11 Implantable prostheses of the prior art include the  
12 Bard PERFIX plug <sup>TM</sup>, Ethicon's Prolene Hernia System  
13 <sup>TM</sup>, and Surgipro Hernia Mate plug and Patch <sup>TM</sup> or  
14 Atrium Self-forming plugs <sup>TM</sup>.

15

16 The Bard PERFIX plug <sup>TM</sup> is one of the most popular  
17 plugs and comprises a surgical mesh fabric arranged  
18 to form around 8 leaves or petals, which are joined  
19 in a central region to create a multi-layered cone.  
20 The central portion of the plug is pushed into the  
21 defect and the leaves trimmed according to the size  
22 of the defect such that they stop the defect. As  
23 the leaves project from the central portion, these  
24 aid the retention of the plug in the defect. In  
25 addition, an overlay patch may be positioned over  
26 the plug which surrounds those tissues surrounding  
27 the inguinal canal. Surgipro Hernia Mate plug and  
28 Patch <sup>TM</sup> and Atrium Self-forming plugs <sup>TM</sup> also  
29 comprise several leaves and an overlay patch and  
30 work in a similar fashion to the Bard product.

31

1 Ethicon's Prolene Hernia System <sup>TM</sup> comprises a first  
2 overlay patch for placing around the inner ring of  
3 the inguinal canal, a central portion and a second  
4 overlay patch for placing around the outer ring of  
5 the inguinal canal. The central portion corresponds  
6 to both a portion of the first and second overlay  
7 patches such that it is held in the inguinal canal  
8 by the two patches to block the canal.

9  
10 In use, the implantable prostheses of the prior art  
11 block the inguinal canal and prevent a hernia sac  
12 from protruding through the canal. The defects  
13 blocked most effectively by the prostheses are  
14 substantially circular in cross section, as multi-  
15 layer prostheses are inherently stiff and may not  
16 fully conform to variations in the defect. In some  
17 circumstances, when a prosthesis is in use, gaps may  
18 be potentially left between the prosthesis and the  
19 surrounding tissue, muscle or organ wall of the  
20 opening or defect.

21  
22 This potential for gaps can be increased by  
23 anatomical structures which under normal  
24 circumstances pass through the inguinal canal, such  
25 as the spermatic cord, and protrude at the edge of  
26 the prosthesis and this causes difficulty in  
27 completely occluding the defect.

28  
29 To improve the flexibility of conventional  
30 prostheses and thus minimise the potential gaps  
31 between the prostheses and surrounding tissues, some  
32 prostheses include pleats moulded into the body of

1 the prostheses. Although, such pleats may to some  
2 extent accommodate anatomical structures which pass  
3 through the defect in the tissue, as such a  
4 prosthesis relies on a push fit of the prosthesis  
5 into the defect and radial expansion of the leaves  
6 of the prosthesis against the tissues surrounding  
7 the defect to hold the implant in place, such a  
8 prosthesis will compress anatomical structures  
9 between the prosthesis and the surrounding tissue.  
10 This compression can result in a significant  
11 pressure being experienced by an anatomical  
12 structure.

13  
14 Significant pressure is a pressure which causes  
15 distortion, compression or full or partial collapse  
16 of an anatomical structure. For example, in  
17 particular examples where a conventional prosthesis  
18 is used to treat inguinal hernia, the spermatic cord  
19 is squeezed between the prosthesis and the tissues  
20 surrounding the aperture and this squeezing may  
21 cause pain or even damage to the spermatic cord.  
22 This can lead to discomfort for the patient and  
23 might lead to long term damage to the structure(s)  
24 being compressed and may cause ischaemia of a distal  
25 organ. For example, where the anatomical structure  
26 includes the spermatic cord, ischaemia of the testes  
27 may occur as a result of compression of the artery  
28 and/or vein along with the spermatic cord.

29  
30 According to the present invention there is provided  
31 a prosthesis for repair or to resist the formation  
32 of hernia of the abdominal wall, the prosthesis

1 comprising at least an outer surface and an inner  
2 surface wherein, the inner surface forms at least  
3 one channel through which, in use, an anatomical  
4 structure may pass when the prosthesis is in place  
5 in the body without substantial compression of said  
6 anatomical structure.

7

8 The channel may be an indentation in the outer  
9 surface of the prosthesis.

10

11 Preferably the channel is formed along the outer  
12 surface of the prosthesis.

13

14 An advantage of a prosthesis of the present  
15 invention is that by providing such a channel in the  
16 prosthesis, pressure on an anatomical structure  
17 passing through the channel can be minimised. A  
18 reduction or complete removal of the pressure on an  
19 anatomical structure should minimise damage and / or  
20 discomfort caused by compression of anatomical  
21 structures passing through the defect being repaired  
22 and minimise the rupture or protrusion of a hernia  
23 sac through the defect.

24

25 In a preferred embodiment of the prosthesis the  
26 inner surface defines a scalloped channel.

27

28 A scalloped channel is formed by the intersection or  
29 indentation of a cylinder with the outer surface of  
30 the prosthesis.

31

32 In a particularly preferred embodiment of the

1 prosthesis the channel has a substantially semi-  
2 circular edge in cross section, such that the inner  
3 surface is substantially curved as it interfaces  
4 with the anatomical structure which the channel  
5 receives.

6

7 Preferably, in use, the prosthesis is always wholly  
8 contained within the extra peritoneal compartment of  
9 the abdominal wall.

10

11 Preferably the prosthesis is suitable for use in the  
12 treatment of abdominal hernia. More preferably the  
13 prosthesis is suitable for treatment of inguinal or  
14 femoral hernia.

15

16 In an embodiment of the prosthesis, the prosthesis  
17 is provided for repairing or resisting the formation  
18 of an inguinal hernia, the channel being sized to  
19 accommodate a spermatic cord without substantial  
20 compression of the spermatic cord.

21

22 In a preferred embodiment of the prosthesis, wherein  
23 the prosthesis is for use in repairing or resisting  
24 the formation of an inguinal hernia, the prosthesis  
25 has a longitudinal length or depth in the range 1 cm  
26 to 5 cm. More preferably the prosthesis has a  
27 longitudinal length in the range of between 2 cm to  
28 3 cm.

29

30 In a preferred embodiment of the prosthesis for use  
31 in repairing or resisting the formation of an  
32 inguinal hernia, the prosthesis is of width or



1 diameter in the range 0.5 cm to 7 cm. In a  
2 particular embodiment the prosthesis is of width or  
3 diameter in the range 1 cm to 4 cm.

4

5 In a particularly preferred embodiment of the  
6 prosthesis for repairing or resisting the formation  
7 of an inguinal hernia, the prosthesis has a  
8 truncated conical shape wherein the outer surface of  
9 the prosthesis is formed by the conic surface.

10

11 A prosthesis of truncated conical shape in which a  
12 first end of the prosthesis has a diameter less than  
13 that of a second end has the advantage that the  
14 prosthesis can be pushed first end into the defect,  
15 to plug the defect more easily.

16

17 In a particularly preferred embodiment, the  
18 prosthesis is of truncated conical shape and further  
19 comprises a semi-circular channel extending from a  
20 first end of the prosthesis to a second end of the  
21 prosthesis, the first end having a diameter less  
22 than the second end, wherein the semi-circular  
23 channel is present in the conic outer surface of the  
24 prosthesis such that in cross-section a crescentic  
25 shaped prosthesis is provided.

26

27 In an embodiment wherein the prosthesis has a  
28 truncated conical shape, the diameter of the widest  
29 end of the prosthesis, the second end, is preferably  
30 in the range 1 cm to 7 cm and the diameter of the  
31 narrowest end, the first end, is preferably in the  
32 range 0.5 cm to 4 cm.

1  
2 The channel receiving the anatomical structure can  
3 have any suitable cross sectional shape such as a  
4 semi-circular cross section. In an embodiment of  
5 the prosthesis for repairing or resisting the  
6 formation of an inguinal hernia, the channel is  
7 sized in the range 0.5 cm to 3 cm in width and depth  
8 or where the channel of such an embodiment of the  
9 prosthesis is of circular or substantially circular  
10 cross section, for example semi-circular cross  
11 section, the channel is in the range 0.5 cm to 3 cm  
12 in diameter.

13  
14 In another embodiment of the prosthesis, the  
15 prosthesis is provided for repairing or resisting  
16 the formation of a femoral hernia. In such an  
17 embodiment the length of the prosthesis is in the  
18 range 1 cm to 5 cm, the width of the prosthesis is  
19 in the range 0.5 cm to 7 cm and the channel is sized  
20 to receive at least one of a femoral vein or other  
21 anatomical structure.

22  
23 In a preferred embodiment of a prosthesis provided  
24 for repairing or resisting the formation of a  
25 femoral hernia the prosthesis is of truncated  
26 conical shape.

27  
28 In an alternative embodiment the prosthesis provided  
29 for repairing or resisting the formation of femoral  
30 hernia is of triangular prism shape. In another  
31 embodiment, in cross section, the prosthesis is  
32 substantially arrowhead shaped having two outer

1 accurate sides which extend from a base towards each  
2 other to form a point. Preferably the point is  
3 rounded. Alternatively, the prosthesis is  
4 substantially D shaped with the accurate sides  
5 forming a more rounded arched point.  
6

7 In a particular embodiment the prosthesis is formed  
8 from a number of component prosthetic parts which  
9 together form the complete prosthesis of the first  
10 aspect of the invention.  
11

12 In an embodiment of the prosthesis formed from at  
13 least two component parts, the parts may include  
14 means to attach the parts to each other to form the  
15 complete prosthesis.  
16

17 It can be envisaged that the component prosthetic  
18 parts are of suitable shape such that in combination  
19 they provide a prosthesis which provides a channel  
20 able to receive an anatomical structure.  
21

22 Typically the prosthesis is formed from resilient  
23 material such that the prosthesis can be flexed to  
24 open the access to the channel.  
25

26 Suitably the prosthesis may be constructed of  
27 synthetic polymer which may be absorbable or non-  
28 absorbable, mesh material formed from synthetic  
29 polymer, solid material, foam or hydrogel. Suitable  
30 synthetic polymers include, but are not limited to,  
31 polyester, polypropylene, PTFE, Mersilene, MPathy-  
32 Mesh <sup>TM</sup> and Mini-Mesh<sup>TM</sup> (available from MPathy

1 Medical Devices Limited, UK).

2

3 The prosthesis may be formed from rolls of mesh  
4 and/or comprises cross members to provide the  
5 prosthesis with strength to resist compression. The  
6 prosthesis may be formed from plastics material. In  
7 a particular embodiment the foam used to construct  
8 the prosthesis is polyurethane.

9

10 This is advantageous in that the channel may be  
11 formed such that, in use, the prosthesis may be  
12 flexed from its rest position to an open position to  
13 increase the width of the access to the channel  
14 enabling an anatomical structure to be more easily  
15 received by the channel. The prosthesis may then be  
16 released to return to its rest position wherein the  
17 anatomical structure is substantially enclosed by  
18 the channel when the prosthesis is located in the  
19 defect.

20

21 An anatomical structure may be partially received  
22 and enclosed by the channel of the prosthesis.  
23 Typically an anatomical structure may be partially  
24 received and enclosed by the channel such that at  
25 least 30% of the circumference of the anatomical  
26 structure is surrounded by the prosthesis.

27

28 The channel of the prosthesis is sized such that in  
29 use an anatomical structure may pass, when the  
30 prosthesis is in place in the body, without  
31 substantial compression of said anatomical structure  
32 by the prosthesis. Substantial compression of the

1 anatomical structure is compression which causes  
2 pain to the patient or ischaemia of a distal organ.  
3 Preferably the width of the anatomical structure,  
4 which in use passes through the channel, is  
5 compressed less than 70%, even more preferably less  
6 than 50%, yet more preferably less than 40%, even  
7 more preferably less than 30%, even more preferably  
8 less than 20%, yet more preferably less than 10%,  
9 even more preferably less than 5%, even more  
10 preferably less than 3%, most preferably less than  
11 1% by the channel of the prosthesis.

12  
13 The level of compression experienced by the  
14 anatomical structure by the prosthesis when the  
15 anatomical structure passes through the channel of  
16 the prosthesis is preferably not more than venous  
17 pressure. Venous pressure is typically in the range  
18 2 to 10 mm Hg.

19  
20 In one embodiment of the prosthesis a single  
21 channel, sized to receive at least one anatomical  
22 structure, is provided. In another embodiment two  
23 channels each sized to receive at least one  
24 anatomical structure, are provided. Each channel may  
25 be differently sized to receive at least one  
26 anatomical structure in order to maximise the  
27 support provided by the prosthesis while allowing  
28 the structure(s) to pass through the one or more  
29 defined channels in the prosthesis.

30  
31 A plurality of channels, each channel sized to  
32 receive one or more anatomical structures, may be

1 received by the prosthesis.

2

3 In a preferred embodiment of the present invention  
4 the prosthesis further comprises at least one flange  
5 provided on either one or both ends of the  
6 prosthesis. The provision of a flange on the  
7 prosthesis is advantageous as it aids location of  
8 the prosthesis in the body and may provide  
9 additional support to tissue, muscle or an organ  
10 wall surrounding the defect. In particular  
11 embodiments, the flange extends from the prosthesis  
12 such that, in use, the flange provides an  
13 inferomedial extension to the prosthesis. For  
14 example, if a prosthesis of the invention further  
15 comprising a flange is used to plug an inguinal  
16 canal, a first end of the prosthesis is positioned  
17 at the internal inguinal ring of the inguinal canal  
18 and a second end of the prosthesis is positioned at  
19 the external ring of the inguinal canal and a flange  
20 present on the second end of the prosthesis, can  
21 inferomedially extend from the prosthesis around the  
22 external ring.

23

24 The flange may be provided by a layer of synthetic  
25 mesh. Alternatively, the flange may be formed from  
26 a plurality of layers of synthetic mesh.

27

28 The layer(s) of mesh may overlap each other.  
29 Moreover, the layer(s) of mesh may be of any desired  
30 shape to support the surrounding tissue, muscle or  
31 organ wall.

32

1 It is advantageous for the flange to be constructed  
2 of mesh. The mesh has minimal mass density in  
3 relation to its volume. In a preferred embodiment  
4 the flange is constructed of Mini-Mesh™.

5  
6 A flange portion may contain structures or regions  
7 capable of receiving sutures or other fixing means  
8 to secure the flange around the anatomical  
9 structures received by the channel and/or to secure  
10 the flange to the surrounding tissue. The flange  
11 may comprise more than one portion of material. For  
12 example, a flange may comprise two or more portions  
13 which can be arranged around an anatomical  
14 structure. The two portions may attach to each  
15 other or overlap each other to form an extended  
16 region of support to a hernia. The portions of the  
17 flange which overlap each other may be formed of  
18 thinner material such that the overlapped region has  
19 the same thickness as the non-overlapped region of  
20 the flange.

21  
22 In a particular embodiment of the prosthesis, the  
23 prosthesis has a crenated outer surface. The  
24 crenated outer surface allows the prosthesis to grip  
25 the tissues surrounding the prosthesis and aids  
26 retention of the prosthesis, in position, in the  
27 body.

28  
29 In a second aspect of the present invention there is  
30 provided a kit of parts including a prosthesis  
31 according to the first aspect of the invention and  
32 synthetic mesh for overlaying the prosthesis when

1 the prosthesis is positioned in the body. The kit  
2 may also include instructions as to the way in which  
3 the components of the kit are to be used.

4

5 According to a third aspect of the invention there  
6 is provided a method for treating a hernia  
7 comprising the steps:

- 8 - exposing the hernia defect
- 9 - providing a prosthesis wholly in the extra  
10 peritoneal compartment of the abdominal wall  
11 to fill the defect but providing a  
12 relatively pressure free passage of an  
13 anatomical structure past the prosthesis.

14

15 The method is for treatment of abdominal hernia.  
16 Typically the method may be used for treatment of  
17 inguinal or femoral hernia.

18

19 The method may further include the step of fixing  
20 the prosthesis to the margins of the defect. One  
21 example of the way in which the prosthesis may be  
22 fixed to the margins of the defect is by suturing.

23

24 The method may further include the step of  
25 overlaying the prosthesis with mesh.

26

27 The method preferably uses the prosthesis of the  
28 first aspect of the invention or the kit of the  
29 second aspect of the invention.

30



1 Preferred features of each aspect of the invention  
2 are as for each of the other aspects mutatis  
3 mutandis unless the context demands otherwise.  
4  
5

6 **Brief Description of the Drawings**  
7

8 Embodiments of the present invention will now be  
9 discussed, by way of example only, with reference to  
10 the accompanying figures in which;  
11

12 Figure 1 shows a perspective view of an  
13 embodiment of a prosthesis of the invention  
14 from a second end;  
15

16 Figure 2 shows a perspective view of an  
17 embodiment of a prosthesis of the invention  
18 from a first end;  
19

20 Figure 3 shows a perspective view of an  
21 embodiment of a prosthesis of the invention in  
22 use;  
23

24 Figure 4 shows an embodiment of a prosthesis  
25 which further includes a flange provided at one  
26 end of the prosthesis;  
27

28 Figure 5 shows an indirect inguinal hernia;  
29

30 Figure 6 shows a hernia repaired using a  
31 conventional prosthesis of the prior art;  
32

1           Figure 7 shows an illustration of the anatomy  
2           around the inguinal canal; and

3  
4           Figure 8 shows an illustration of the anatomy  
5           around the femoral canal.

6

7           **DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS**

8

9           The invention is directed to an implantable  
10          prosthesis for repairing or resisting the formation  
11          of bodily hernia, in particular to plug or stop any  
12          aperture in the body in which a structure is  
13          required to pass through or adjacent to the  
14          aperture. For example, the prosthesis may be used  
15          to plug the inguinal canal or the femoral canal. In  
16          these embodiments, provided by way of example only,  
17          the prosthesis has a channel through which an  
18          anatomical structure, such as a spermatic cord or  
19          femoral vein, may pass without substantial  
20          compression of the anatomic structure.

21

22          As shown in figures 1 and 2, in one embodiment, the  
23          prosthesis 10 is a truncated cone having a first end  
24          14 and a second end 16, wherein the diameter of the  
25          first end is less than the diameter of the second  
26          end 16, and an outer conic surface 15 extends  
27          between the ends. An inner surface 12 forming a  
28          channel is defined by a substantially scalloped  
29          portion removed from the outer surface of the  
30          truncated conical prosthesis. It can be envisaged  
31          that the scalloped portion is formed by the removal  
32          of a cylindrical portion which intersects the outer

1 conical surface 15 to create a prosthesis of  
2 crescential cross-section. The prosthesis resembles  
3 a wedge shape being narrower at the first end and  
4 widest at its second end. An anatomical structure  
5 may pass through the prosthesis whilst being  
6 partially surrounded by the prosthesis to minimise  
7 the pressure or compression exerted on the  
8 anatomical structure.

9  
10 It will be understood that the cross section of the  
11 channel may be formed by at least one straight edge  
12 such that the inner surface has a straight portion  
13 in cross section, for example a box section channel  
14 or at least one curved edge, to form a semi-circular  
15 channel or other shapes as should be apparent to one  
16 skilled in the art.

17  
18 The channel 12 in the outer conical surface 15 of  
19 the prosthesis 10 is sized to receive an anatomical  
20 structure(s) which passes through the defect to be  
21 repaired or supported. As shown in the illustrated  
22 embodiment, figure 3, the channel formed by inner  
23 surface 12 receives an anatomical structure 30 such  
24 that the anatomical structure is partially located  
25 in the channel. The channel minimising the  
26 compression of the anatomical structure against the  
27 edges of the defect when, in use, the prosthesis is  
28 located in the body.

29  
30 In the embodiment of the prosthesis illustrated in  
31 figures 1 to 3 for use in repair of an inguinal  
32 hernia the prosthesis is of truncated conical shape

1 with a semi-circular channel removed from the  
2 conical surface such that the prosthesis is  
3 substantially a wedge shape extending from a first  
4 end 14 of minimal depth to a second end of diameter  
5 of around 19 mm. The channel is of around 15 mm in  
6 depth at the second end, such that in cross-section  
7 the second end is crescential in shape with a  
8 maximum depth (x - y see figure 1) of 7 mm. The  
9 length of the prosthesis between the first and  
10 second ends is around 23mm.

11

12 The portion removed from the truncated conical  
13 prosthesis to provide a channel can be in the range  
14 of 5 mm to 20 mm in width and depth. Although in  
15 the embodiment shown in figures 1 to 3, the channel  
16 is substantially semi-circular in cross section, the  
17 channel may be of any shape. In addition, more than  
18 one channel may be present in the prosthesis, each  
19 channel being able to receive a particular  
20 anatomical structure.

21

22 Typically the prosthesis is in the range 1 cm to 5  
23 cm in length between the ends and around 1 cm to 4  
24 cm in width and depth.

25

26 As shown in figure 3, in use, an anatomical  
27 structure 30 is received by the channel 12, the  
28 channel indenting the conical surface of the  
29 prosthesis and linking the first and second ends 14  
30 and 16, such that the anatomical structure can pass  
31 from one end of the prosthesis to the other without  
32 substantial compression. This differs from the

1 conventional prosthesis 100, illustrated in figure  
2 6, which lacks a channel. As illustrated in figure  
3 6 when a conventional prosthesis is in use to plug a  
4 defect, for example in abdominal wall muscle 36 and  
5 fat 34 through which a hernia 32 of viscous 38  
6 protrudes, an anatomical structure 30, such as a  
7 spermatic cord, is located between the prosthesis  
8 100 and the edge of the defect. As the prosthesis  
9 100 lacks a channel and the prosthesis is pushed  
10 into the defect, the anatomical structure is  
11 compressed.

12  
13 The prosthesis and further the flange portion may be  
14 formed from a range of material including, but not  
15 limited to, polyester, polypropylene, PTFE,  
16 Mersilene, MPathy-Mesh™ or Mini-Mesh™ (available  
17 from MPathy Medical Devices Limited, UK).

18  
19 The prosthesis may be formed using suitable  
20 construction techniques, for example knitting and /  
21 or weaving of monofilament or multifilament yarns,  
22 moulding, ultrasonic, induction, vibration, infrared  
23 or laser welding.

24  
25 As illustrated in figure 4, the prosthesis of the  
26 present invention may further comprise a flange 18.  
27 The flange may extend laterally from at least a  
28 first or second end or both ends of the prosthesis.

29  
30 As shown in figure 4, when the prosthesis is located  
31 in the defect, the flange 18, which extends from the  
32 second end of the prosthesis, can aid the

1 positioning of the prosthesis, in the inguinal  
2 canal. Further, the flange may be formed from mesh  
3 and extend from the prosthesis such that when the  
4 prosthesis is implanted in the body the mesh extends  
5 to the musculature surrounding the inguinal canal  
6 and provides support thereto. In particular  
7 embodiments, the flange can extend from the  
8 prosthesis inferomedially, which aids the use of the  
9 prosthesis in the treatment of direct inguinal  
10 hernia.

11  
12 The flange may include more than one layer of mesh  
13 and said layers may overlap each other. Moreover,  
14 the flange may include cut out portions to allow it  
15 to be placed around or over protruding structures or  
16 attachment means to attach the flange to itself and  
17 / or tissue, muscle etc. Such attachment means  
18 include sutures or other fixing means.

19  
20 In embodiments wherein a flange is provided on both  
21 ends of the prosthesis, the flange, when the  
22 prosthesis is in use, may be provided around the  
23 internal ring and external ring of the inguinal  
24 canal such that the tissue and fascia around the  
25 inguinal ring is sandwiched between at least two  
26 layers of mesh. The flange thus supports the tissue  
27 and/or fascia and minimises the likelihood of organs  
28 or structures rupturing or protruding through the  
29 tissue and/or fascia.

30  
31 An embodiment of the prosthesis of the first aspect  
32 of the invention can be utilised to repair or resist

1 the formation of an inguinal canal.

2

3 As illustrated in figures 7 and 8 the sac of an  
4 indirect inguinal hernia 40 may extend from the  
5 external ring 42 of the inguinal canal 44. The  
6 inguinal canal extending between the external ring  
7 42 and an internal ring 46.

8

9 In use, a prosthesis is inserted into the inguinal  
10 canal such that a first end of the prosthesis is  
11 positioned at the internal inguinal ring 46 and the  
12 second end is positioned at the external ring 42 of  
13 the inguinal canal. When located in the inguinal  
14 canal 44 the prosthesis acts to minimise the  
15 protrusion of organs or the other body parts through  
16 the inguinal canal, but as the prosthesis includes a  
17 channel, there is provided a passage for selected  
18 anatomical structures, such as the spermatic cord,  
19 to pass through the prosthesis without being  
20 substantially compressed by the prosthesis or  
21 between the prosthesis and the surrounding tissue.

22

23 To aid the fixation of the prosthesis in the  
24 inguinal canal the prosthesis may be crenated on its  
25 outer surface. Such crenations will project from the  
26 outer surface of the prosthesis into the surrounding  
27 tissue and minimise the movement of the prosthesis  
28 once it has been suitably positioned.

29

30 An embodiment of the prosthesis of the invention may  
31 be used to repair or resist the formation of a  
32 femoral hernia. As illustrated in figures 7 and 8

1 the femoral canal 48 lies between the fascia  
2 transversalis 50 and fascia iliaca 52 with the  
3 femoral vein 54, femoral artery 56 and femoral nerve  
4 58 being present to one side of the femoral canal.  
5 As shown in figure 7, a sac of a femoral hernia 60  
6 may extend along and pass out of the femoral canal.

7  
8 In use, an embodiment of the prosthesis for  
9 treatment of femoral hernia may be inserted into the  
10 femoral canal to minimise the protrusion of the  
11 hernia sac through the femoral canal. During  
12 insertion of the prosthesis into the femoral canal,  
13 the channel of the prosthesis is orientated such  
14 that expansion of the femoral vein is into the  
15 channel of the prosthesis. Thus, in contrast to  
16 conventional prosthesis, the compression of the  
17 expanded vein against the prosthesis and / or the  
18 surrounding tissue will be minimised. In addition,  
19 the channel will still provide for movement in the  
20 lymphatic system from a lower limb to external iliac  
21 nodes.

22  
23 In one embodiment, a prosthesis of the present  
24 invention, for use in plugging the femoral canal, is  
25 substantially of triangular prism shape in cross  
26 section such that it is shaped to fit into the  
27 femoral canal. In another embodiment, in cross  
28 section, the prosthesis is substantially arrowhead  
29 shaped having two outer accurate sides which extend  
30 from a base towards each other to form a point.  
31 Preferably the point is rounded. Alternatively, the  
32 prosthesis is substantially D shaped with the



1 accurate sides forming a more rounded arched point.  
2 In each embodiment a channel is provided in the  
3 outer surface of the prosthesis to receive the  
4 femoral vein when it is expanded. When the  
5 prosthesis is substantially arrowhead or D shaped,  
6 it is preferred that the base portion is indented  
7 towards the point to receive an anatomical  
8 structure.

9  
10 The prosthesis is sized such that it can be suitably  
11 located into the femoral canal. In particular  
12 embodiments the prosthesis is sized such that it is  
13 of length in the range 1 cm to 5 cm, of width at a  
14 first end for insertion into the femoral canal in  
15 the range 0.5 cm to 3 cm and a second end at 0.5 cm  
16 to 5 cm.

17  
18 The channel need only be an indentation in the outer  
19 surface of the prosthesis to receive the femoral  
20 vein when expanded such that the pressure exerted on  
21 the vein, during expansion of the vein, by the  
22 prosthesis is minimised.

23  
24 As discussed above, a prosthesis for use in treating  
25 femoral hernia may further include a flange at  
26 either or both ends of the prosthesis, wherein the  
27 flange extends around the femoral canal and thus  
28 supports the surrounding tissue or fascia. As  
29 previously discussed such a flange may also contain  
30 cutouts to accommodate structures such as the  
31 femoral nerve and / or artery.

32

1 The prosthesis of the present application has been  
2 designed to take into consideration the anatomical  
3 structures and properties of the inguinal and  
4 femoral canal to minimise the disruption of these  
5 structures following location of the prosthesis.

6  
7 Various modifications can be made without departing  
8 from the scope of the invention, for example,  
9 flanges extending from the faces of the prosthesis,  
10 as discussed above, may be formed from material with  
11 memory, such that following placement in the body  
12 the flanges move from a collapsed position to an  
13 extended position to secure the prosthesis in the  
14 body.